

REMARKS/ARGUMENTS

Claims 1, 3-6, 9-21, and 24-30 are pending in this application. Claims 1 and 20 have been amended to further define the term “substantially cover,” and support for such amendment can be found on page 7, lines 11-13 of the specification. Claims 1, 15, 17, 18, 20, and 21 have been amended to replace “at least about” with the term “at least.” Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

Provisional Double Patenting Rejection

Claims 1, 4, and 9-12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15, 19, and 26 of copending application no. 10/697,546 (the ‘546 Application) in view of Clemente (US patent No. 6,126,967). See Pages 2-4 of the Office Action. The ‘546 Application is still pending in the U.S. Patent Office and has not issued as a patent. Additionally, Applicant expects that this provisional double patenting rejection will be the only rejection remaining following consideration of this amendment. As set forth in MPEP §804(a):

... "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent.

Applicants, therefore, respectfully request withdrawal of this provisional rejection.

Rejections Under 35 USC 112, Second Paragraph

I

Claim 1 is rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. See page 5 of Office Action. According to the Office Action on page 5, the “term ‘substantially’ in claim 1 is a relative term which renders the claim

indefinite.” Applicants respectfully disagree. However, in the interest of furthering this application to allowance, Applicants have amended claim 1 as discussed above. Claim 12 did not recite this term. Accordingly, Applicants respectfully request this rejection be withdrawn.

II

Claims 1, 12, 15, 17, 18, 20, and 21 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. See page 5 of Office Action. See page 5 of Office Action. According to the Office Action on page 5, it is “unclear to the examiner if ‘at least’ or ‘about’ is the intended value.” Applicants respectfully disagree. However, in the interest of furthering this application to allowance, Applicants have amended claims 1, 15, 17, 18, 20, and 21 as discussed above. Claim 12 did not recite this term. Accordingly, Applicants respectfully request this rejection be withdrawn.

Rejections Under 35 USC 103

Claims 1, 3-6, 9-21 and 24-30 were rejected under 35 USC 103(a) as being unpatentable over Shah et al. (US 6,126,969) in view of Singh et al. (US 5,759,579) and Clemente et al (US 6,126,967). See pages 6-12 of Office Action. According to the Office Action:

“Singh teaches a pharmaceutical acceptable liquid suspension system provided for solid finely divided pharmaceutical actives Singh teaches various examples of liquid suspension systems in columns 4-7 wherein the concentrations of the drug is about 3.2% and the water content is at least 40%. . . . The difference between the invention of the instant application and that of Singh is that the instant invention claims the use of particles of an NSAID and/or acetaminophen being coated with a controlled release composition as opposed to being uncoated and used for immediate release. For this reason, the teaching of Shah et al. is joined. Shah et al. teach an orally administrable sustained-release dosage form that includes particles of an active pharmaceutical ingredient which is coated with a polymeric material that is water-insoluble, but water-permeable and water-swellable. Another difference between the invention of the instant application and that of Singh is that the instant invention claims the use of a controlled release composition comprising an insoluble film-forming polymer and an enteric polymer wherein the weight of the insoluble film

forming polymer and the enteric polymer is from about 80:20 to about 99:1 as opposed to being silent. For this reason, the teaching of Clemente et al. is joined. Clemente et al teach an extended release composition comprising acetaminophen particles coated with each of the first, second and third layer, the first and third layers being hydroxypropyl cellulose and the second layer being ethylcellulose wherein the weight ratio of each the first, second, and third layers on a bead is about 1:4-6:1, respectively (col. 4, lines 36-42). . . . It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the cited references to arrive at a pharmaceutical liquid suspension dosage form comprising particles of an NSAID and/or acetaminophen being substantially covered with one layer of a controlled release composition. (emphasis added)"

Applicants respectfully disagree. Independent claims 1 and 20 recite a pharmaceutical liquid suspension dosage form comprising particles of an NSAID and/or acetaminophen, wherein at least 99% of said particles are covered with one layer of a controlled release composition wherein said controlled release composition is comprises of an insoluble film forming polymer and an enteric polymer, wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1. The benefit of such a coating is that (i) it protects the particles from dissolution in the suspension and (ii) when it enters the intestinal tract, the relatively lesser amount of the enteric polymer dissolves, creating openings in the layer that still comprises the insoluble film forming polymer through which the NSAID and/or acetaminophen can be released. Such a coated particle, and accordingly a suspension containing such a particle, is not taught, nor suggested, by the above references alone or in view of each other.

As discussed above, Singh fails to disclose controlled release coated particles. Further, neither Shah et al. nor Clemente et al. disclose the coating of particles with an enteric polymer. The Office Action asserts that Clemente et al. discloses enteric polymers, but no support for such assertion (e.g., column and line numbers) is provided. In any event, as acknowledged in the Office Action, Clemente et al. discloses particles coated with a first, a second, and the third layer, wherein the first and third layers being hydroxypropyl cellulose and the second layer being ethylcellulose. Neither hydroxypropyl cellulose nor ethylcellulose are enteric polymers. Further, as discussed above, this particle is not the same type of coated particle as in the pending claims, which requires both a insoluble film forming polymer and an enteric polymer in the same layer, wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1. This way, as discussed above, openings will be created in the layer when the enteric polymer dissolve through which the NSAID and/or

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acetaminophen can be released. . Such a coated particle, and accordingly a suspension containing such a particle, is not taught, nor suggested, by the above references alone or in view of each other.

Accordingly, Applicants assert that the presently claimed invention would not have been obvious to a person of ordinary skill in the art at the time of the claims invention was made in light of these references. Thus, Applicants respectfully request that this rejection under 35 USC 103(a) be withdrawn.

Conclusion

For the foregoing reasons, the present application is in condition for allowance. Accordingly, favorable reconsideration of the amended claims in light of the above remarks and an early Notice of Allowance are courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned Attorney at the below-listed number.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 10-0750/MCP5021/WEM.

Respectfully submitted,

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